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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,257	10/19/2000	Philip W. Miller	38-21(15771)B	7102
7590	05/31/2006			EXAMINER TUNG, JOYCE
Lawrence M. Lavin, Jr. MONSANTO COMPANY Mailzone E2NA 800 N. Lindbergh Boulevard St. Louis, MO 63167			ART UNIT 1637	PAPER NUMBER
DATE MAILED: 05/31/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/692,257	MILLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 March 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 8-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

The applicant's request for continued examination filed 3/29/06 has been entered. Claims 1 and 8-13.

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/29/2006 has been entered.

### ***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1 and 8-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

The claimed invention is not supported by a specific utility because the disclosed uses of the polynucleotide are not specific and are generally applicable to any polynucleotide. The specification discloses many potential uses for the polynucleotide including identifying promoters involved in gene regulation (pg. 37, lines 13-27 to pg. 38, lines 1-6), determining whether a plant contains a mutation (pg. 14, lines 10-27 to pg. 15, lines 1-12 and pg. 38, lines 7-27), and acting as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (pg. 46, lines 4-46). These are non-specific uses that are applicable to

polynucleotides in general and not particular or specific to the polynucleotide claimed. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case none of the promoters, mutations, or genes that are to be identified as final products resulting from processes involving claimed nucleic acid have asserted or identified specific and substantial utilities. The research contemplated by the applicants to characterize potential promoters, mutations, and genes does not constitute a specific and substantial utility. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polynucleotides such that another non-asserted utility would be well established for the compounds.

***Claim Rejections - 35 USC § 112, first paragraph (Enablement)***

4. Claims 1 and 8-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a “specific or substantial” asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *re Wands*, 8 USPQ2d 1400 (CA FC 1988). *Wands* states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The claims are drawn to a substantially purified nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO:1 or its complement. The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." *Mycogen Plant Sci., Inc. v. Monsanto Co.*, 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

The claims broadly any variants and fragment of SEQ ID NO: 1 DNA, predicting protein structure from sequence data

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely difficult. It would require significant study to identify the actual function of the maize protein, and identifying a use for this protein would be an inventive, unpredictable and difficult undertaking in itself. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. the sites or regions directly involved in binding, activity and in providing the

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correct three-dimensional spatial orientation of binding and active sites, and determinants of antigenicity. These regions can tolerate only relatively conservative substitute or no substitute (See Wells, Biochemistry, 1990, 29, pg. 8509-8517; Ngo et al. The Protein Folding Problem and Tertiary Structure Prediction, pg. 492-495).

This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

The unpredictability of the art and the state of the prior art

The art is extremely unpredictable with regard to protein function in the absence of reliable information regarding the protein function.

Working Examples

The specification has working example in which cDNA libraries are constructed but the working example lacks sufficient information regarding how the nucleic acid molecule that encodes a maize protein or fragment comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement is purified.

Guidance in the Specification.

Applicant has provided little or no guidance beyond the presentation of sequence data to enable one of ordinary skill in the art to determine the positions in the protein, which are tolerant to change (e.g. amino acid substitutions or deletions). Thus, the specification did not teach any actual function of the nucleic acid sequence of SEQ ID NO: 1 and its complement.

Level of Skill in the Art

The level of skill in the art is deemed to be high.

Conclusion

Although the specification outlines art-recognized procedures for producing and screening for active muteins, this is not an adequate guidance as to the nature of active derivatives that may be constructed, but is an invitation to the artisan to use the current invention as a starting point for further experimentation. The art recognizes that function cannot be predicted from structure alone (Bork, Genome Research 2000, 10, pg. 398-400; Skolnick et al. Trends in Biotech, 2000, 18(1), pg. 34-39, especially p. 36 at Box 2; Doerks et al. Trends in Genetics, 1998, 14: pg. 248-250; Smith et al, Nature Biotechnology, 1997, 15: pg. 1222-1223; Brenner, Trends in Genetics, 1999, 15: pg. 132-133; Bork, Trends in Genetics, 1996, 12: pg. 425-427). Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims, the claims fail to recite any structural or functional limitations, undue experimentation would be required by the skilled artisan to make and/or use the claimed invention in its full scope.

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of that art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the presence of a working example which does not address the issue of the utility of the claimed nucleic acid molecule that encodes a maize protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 1 or its complement. It is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

***Claim Rejections - 35 USC § 112, first paragraph (Written Description)***

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5. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to a maize protein. The breadth of enablement is not commensurate in scope with the claims. The specification discloses very narrow working examples as compared to the wide breath of the claims at issue. Furthermore, EST technology is highly unpredictable. Thus, the teachings set forth in the specification provides no more than a "plan" or "invitation" for those skilled in the art to experiment using the technology in other type of cells.

### **Summary**

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. T.*  
May 25, 2006

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER

5/25/06